

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: METOPROLOL SUCCINATE
END-PAYOR ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:
INDIRECT END-USER ACTION

Civil Action No. 06-cv-71 (GMS)

**END-PAYOR PLAINTIFFS' BRIEF IN SUPPORT OF UNOPPOSED MOTION FOR
PRELIMINARY APPROVAL OF PROPOSED SETTLEMENT**

CHIMICLES & TIKELLIS LLP

Pamela S. Tikellis (#2172)

A. Zachary Naylor (#4439)

P.O. Box 1035

222 Delaware Avenue, Suite 1100

Wilmington, DE 19801

(302) 656-2500

Liaison Counsel for Class Plaintiffs

[Interim Co-Lead Counsel on signature page]

Dated: September 25, 2012

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
I. INTRODUCTION.....	1
II BACKGROUND.....	2
III THE PROPOSED SETTLEMENT AGREEMENT	3
IV. THE CLASS SHOULD BE CONDITIONALLY CERTIFIED FOR SETTLEMENT PURPOSES.....	4
A. The Requirements Of Rule 23(a) Are Satisfied.....	5
B. The Requirements Of Rule 23(b)(3) Are Satisfied	6
1. Common Legal and Factual Questions Predominate	7
2. Superiority	8
C. The Court Should Appoint Class Counsel And Liaison Counsel	8
V. THE PROPOSED SETTLEMENT SHOULD BE PRELIMINARY APPROVED.....	9
A. The Settlement Is Entitled To A Presumption Of Fairness.....	9
B. The Settlement Falls Within The Range Of Possible Approval	11
VI. THE NOTICE PROGRAM SHOULD BE APPROVED.....	13
A. Notice Plan Description	13
B. The Proposed Form And Manner Of Notice Are Appropriate	16
1. Notice to TPP Class Members	16
2. Notice to Consumer Class Members	17
3. The Form and Content of the Notices Should Be Approved.....	18
C. Proposed Schedule	19
VII. CONCLUSION.....	20

TABLE OF AUTHORITIES

	Page(s)
FEDERAL CASES	
<i>Amchem Prods., Inc. v. Windsor</i> , 521 U.S. 591 (1997)	5
<i>Austin v. Pennsylvania Dep't of Corrections</i> , 876 F. Supp. 1437 (E.D. Pa. 1995)	11
<i>Collier v. Montgomery County</i> , 192 F.R.D. 176 (E.D. Pa. 2000).....	11
<i>Columbus Drywall & Insulation, Inc. v. Masco Corp.</i> 2009 WL 856306 (N.D. Ga. Feb. 9, 2009)	6
<i>Curiale v. Lenox Group, Inc.</i> , 2008 WL 4899474 (E.D. Pa. Nov. 14, 2008)	10
<i>Gates v. Rohm & Haas Co.</i> , 248 F.R.D. 434 (E.D. Pa. 2008)	9
<i>In re Buspirone Patent Litig.</i> , 210 F.R.D. 43 (S.D.N.Y. 2002)	8
<i>In re Cardizem CD Antitrust Litig.</i> , 218 F.R.D. 508 (E.D. Mich. 2003).....	5
<i>In re Cendant Corp. Litig.</i> , 264 F.3d 201 (3d Cir. 2001)	10
<i>In re Cmty Bank of N. Virginia</i> , 622 F.3d 275 (3d Cir. 2010)	6
<i>In re Flat Glass Antitrust Litig.</i> , 191 F.R.D. 472 (W.D. Pa. 1999)	7
<i>In re Flonase Antitrust Litig.</i> , 2012 WL 2277840 (E.D. Pa. June 18, 2012).....	8
<i>In re Gen. Motors Corp. Pick-up Truck Fuel Tank Prods. Liab. Litig.</i> , 55 F.3d 768 (3d Cir. 1995)	10
<i>In re HealthSouth Corp. Sec. Litig.</i> , 334 Fed. App'x. 248 (11th Cir. 2009).....	4
<i>In re K-Dur Antitrust Litig.</i> , 2008 WL 2699390 (D.N.J. Apr. 14, 2008)	8
<i>In re Lorazepam & Clorazepate Antitrust Litig.</i> , 202 F.R.D. 12 (D.D.C. 2001).....	7
<i>In re Lupron Mktg. and Sales Practices Litig.</i> , 228 F.R.D. 75 (D. Mass. 2005)	5
<i>In re Neurontin Antitrust Litig.</i> , 2011 WL 286118 (D.N.J. Jan. 25, 2011)	8
<i>In re Nissan Motor Corp. Antitrust Litig.</i> , 552 F.2d 1088 (5th Cir. 1977).....	18
<i>In re Packaged Ice Antitrust Litig.</i> , 2011 WL 717519 (E.D. Mich. Feb. 22, 2011).....	12
<i>In re Plastic Cutlery Antitrust Litig.</i> , 1998 WL 135703 (E.D. Pa. Mar. 20, 1998)	6

<i>In re Prudential Ins. Co. of Am. Sales Practices Litig.</i> , 148 F.3d 283 (3d Cir. 1998).....	20
<i>In re Relafen Antitrust Litig.</i> , 231 F.R.D. 52 (D. Mass. 2005)	5, 14
<i>In re Remeron End-Payor Antitrust Litig.</i> , 2005 WL 2230314 (D.N.J. Sept. 13, 2005)	5, 9, 14, 17
<i>In re Remeron Direct Purchaser Antitrust Litig.</i> , 2005 WL 3008808 (D.N.J. Nov. 9, 2005).....	14
<i>In re Urethane Antitrust Litig.</i> , 237 F.R.D. 440 (D. Kan. 2006)	8
<i>In re Warfarin Sodium Antitrust Litig.</i> , 212 F.R.D. 231 (D. Del. 2002), <i>aff'd</i> , 391 F.3d 516 (3d Cir. 2004).....	6-10, 13, 18, 19
<i>Larson v. AT&T Mobility</i> , 687 F.3d 109 (3d Cir. 2012).....	18
<i>Louisiana Wholesale Drug Co. et al. v. Abbott Labs. et al.</i> , Civ. No. 05-340 (D. Del.)	14
<i>Mack Trucks, Inc. v. Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am.-UAW</i> , 2011 WL 1833108 (E.D. Pa. May 12, 2011).....	12
<i>Mehling v. New York Life Ins. Co.</i> , 246 F.R.D. 467 (E.D. Pa. 2007)	10
<i>Meijer Inc. et al. v. AstraZeneca Pharm. LP et al.</i> , No. 06-52-MPT (D. Del. Feb. 21, 2012)	13
<i>Milliron v. T-Mobile USA, Inc.</i> , 2009 WL 3345762 (D.N.J. Sept. 10, 2009), <i>aff'd</i> , 423 Fed. App'x. 131 (3d Cir. 2011)	11
<i>Nichols v. SmithKline Beecham Corp.</i> , 2005 WL 950616, at *7 (E.D. Pa. Apr. 22, 2005)	5
<i>Painters Dist. Council No. 30 Health & Welfare Fund v. Abbott Labs.</i> , No. 05-360 (D. Del.).....	14
<i>Samuel v. Equicredit Corp.</i> , 2002 WL 970396 (E.D. Pa. May 6, 2002)	12
<i>Sullivan v. DB Invs., Inc.</i> , 667 F.3d 273 (3d Cir. 2011)	5, 7, 8
<i>Teva Pharms. USA, Inc. v. Abbott Labs.</i> , 252 F.R.D. 213 (D. Del. 2008)	8
<i>Thomas v. NCO Fin. Sys., Inc.</i> , 2002 WL 1773035 (E.D. Pa. July 31, 2002).....	10
<i>Thomas v. NCO Fin. Sys., Inc.</i> , 2004 WL 727071 (E.D. Pa. Mar. 31, 2004).....	18
<i>Varacallo v. Massachusetts Mut. Life Ins. Co.</i> , 226 F.R.D. 207 (D.N.J. 2005)	10
<i>VistaHealth Plan, Inc. v. Bristol-Myers Squibb Co.</i> , 287 F. Supp. 2d 65 (D.D.C. 2003)	17

Zimmer Paper Prods., Inc. v. Berger & Montague P.C., 758 F.2d 86 (3d Cir. 1985).....17

RULES and STATUTES

Fed. R. Civ. P. 23..... passim

Class Action Fairness Act of 2005, 28 U.S.C. § 1715.....20

Clayton Act, Section 16, 15 U.S.C. § 262

Health Insurance Portability and Accountability Act of 1996 (HIPAA),
Public Law 104-91, 45 C.F.R. Part 160, and Part 164 Subparts A and E18

I. INTRODUCTION

End-Payor Plaintiffs submit this Brief in support of their unopposed motion seeking preliminary approval of a proposed class action settlement with Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB, and Aktiebolaget Hassle (collectively “AZ”), as well as related relief described in detail below.¹ A copy of the Settlement Agreement, dated July 2, 2012 (“SA”), is attached as Exhibit 1 to End-Payor Plaintiffs’ Unopposed Motion For Preliminary Approval Of Proposed Settlement (the “Motion”). *See* Fed. R. Civ. P. 23(e)(3). Defendants support the relief requested in Plaintiffs’ Motion. *See* SA ¶ 2.

The proposed settlement provides for the payment of up to \$11 million for the benefit of Plaintiffs and members of the proposed Settlement Class (defined below), in exchange for dismissal of this litigation with prejudice and a release of claims from Plaintiffs and all members of the proposed Settlement Class (the “Settlement”). The Settlement was achieved after many years of litigation that included extensive discovery and motion practice, substantial and thorough expert analysis, and settlement negotiations facilitated by a Court-appointed mediator. Settlement negotiations were conducted in good faith at arm’s-length over an extended period of time by highly experienced counsel. Because the litigation was in an advanced procedural posture, counsel had all relevant facts disclosed during discovery at their disposal in making settlement assessments and in crafting and finalizing the Settlement. The Settlement assures that Plaintiffs and the Settlement Class will receive substantial benefits, while avoiding the

¹ End-Payor Plaintiffs (hereafter, “Plaintiffs”) are: A.F. of L. – A.G.C. Building Trades Welfare Plan; the American Federation of State, County, and Municipal Employees District Council 47 Health and Welfare Fund; District 1199P Health and Welfare Plan; International Association of Fire Fighters Local 22 Health and Welfare Fund; National Joint Powers Alliance; Plumbers and Pipefitters Local 572 Health and Welfare Fund; United Food and Commercial Workers Union Local 1776 and Participating Employers Health and Welfare Fund; United Union of Roofers, Waterproofers and Allied Workers, Local No. 74 Health and Pension Fund; United Union of Roofers, Waterproofers and Allied Workers, Local No. 203 Health and Pension Fund; Mary Anne Gross; Neil Lefton; and Mark S. Merado.

uncertainties of continued litigation and trial. For these reasons, as set forth more fully below, the Settlement merits preliminary approval and notice to the Class.

Plaintiffs therefore respectfully request that the Court enter an order, substantially in the form of the proposed Preliminary Approval Order attached as Exhibit 2 to the Motion:

(i) conditionally certifying the Class for settlement purposes; (ii) conditionally appointing Kessler Topaz Meltzer & Check, Fine Kaplan and Black, and Pomerantz Haudek Grossman & Gross as Co-Lead Class Counsel, and Chimicles & Tikellis as Liaison Counsel; (iii) conditionally appointing the named Plaintiffs as Class Representatives; (iv) preliminarily approving the proposed Settlement; (v) approving the proposed form and manner of notice; (vi) appointing Rust Consulting, Inc. as the Settlement Administrator; and (vii) adopting the proposed schedule for completing the approval process, submissions of claims, objections, exclusions, filing of final approval submissions, and a fairness hearing.

II. BACKGROUND

This antitrust class action was filed in 2006 by consumers and third-party payors who purchased, paid and/or reimbursed others for the hypertension medication Toprol-XL (metoprolol succinate). Plaintiffs allege that AZ prevented generic versions of Toprol-XL from entering the market by manipulating patent filings and prosecuting baseless patent infringement lawsuits, thus unlawfully monopolizing and/or attempting to monopolize the domestic market for Toprol-XL and its generic equivalents. Plaintiffs assert claims for declaratory and injunctive relief under Section 16 of the Clayton Act for AZ's violations of Section 2 of the Sherman Act; for damages under the statutes of the indirect purchaser states; for unfair and deceptive trade practices under state law; and for unjust enrichment. *See* First Am. Consol. Class Action Compl. (D.I. 276).

The Settlement was achieved after several years of hard-fought litigation during which a voluminous discovery record was compiled. AZ produced nearly one million pages of documents; multiple and lengthy interrogatory responses were exchanged; more than two dozen fact and expert witnesses were deposed; twelve experts submitted reports addressing economic, patent, pharmaceutical, regulatory and damages issues; and third-party discovery was obtained from three manufacturers of generic metoprolol succinate.

The parties thoroughly analyzed the legal and factual issues presented in this complex litigation. That analysis is reflected in part in the hundreds of pages of briefing filed over the past six years addressing AZ's two motions to dismiss (D.I. 24 & 294), AZ's motion for judgment on the pleadings (D.I. 153), AZ's motion to stay the litigation (D.I. 258), Plaintiffs' motion for class certification (D.I. 100), Plaintiffs' motions to amend the complaint (D.I. 166 & 302), AZ's motion *in limine* to exclude expert testimony (D.I. 295), the parties' positions on trial consolidation and bifurcation (D.I. 205 & 206), and the parties' requests for permission to file summary judgment and *Daubert* motions (D.I. 269 & 271).

The significantly developed record in this case informed the substantive negotiations between the parties. Those negotiations were extensive and conducted at arms'-length by experienced counsel for Plaintiffs and AZ, and occurred primarily with the assistance and supervision of a Court-appointed mediator during several in-person and telephonic mediation sessions.

III. THE PROPOSED SETTLEMENT AGREEMENT

The Settlement provides for a total cash payment of up to \$11 million in settlement of this litigation. SA ¶ 6. Of that total amount, up to \$1 million is to be used exclusively for the

cost of class notice and claims administration, with any unused portion of those earmarked funds to be returned to AZ. The settlement is binding on the proposed Settlement Class, defined as:

All persons or entities throughout the United States and its territories who indirectly purchased, paid for and/or reimbursed others for Toprol XL or its generic equivalent metoprolol succinate, intended for consumption by themselves, their families or their members, employees, plan participants, beneficiaries or insureds at any time from May 5, 2005 through the date of entry of a Court order preliminarily approving the proposed settlement of this action (the "Class Period").

SA ¶ 1.² In exchange for the cash payment, the Settlement Class will provide AZ with a release of all claims relating in any way to the alleged conduct or omissions that gave rise to this action.

SA ¶ 11.a. Final approval of the Settlement will result in the dismissal with prejudice of Plaintiffs' claims against AZ. *See id.* ¶¶ 4.e & 5.³

IV. THE CLASS SHOULD BE CONDITIONALLY CERTIFIED FOR SETTLEMENT PURPOSES

Before addressing the adequacy of a proposed settlement, the court must determine that the class may be certified for purposes of settlement. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613 (1997); *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 296 (3d Cir. 2011). Certification of a settlement class is appropriate where, as here, the requirements of Rule 23(a) and 23(b) are

² The following persons or entities are excluded from the proposed Class: (i) Defendants and their respective subsidiaries and affiliates; (ii) all governmental entities (except government funded employee benefit plans); (iii) all persons or entities who purchased metoprolol succinate, including Toprol XL, directly from Defendants; (iv) insured individuals covered by plans imposing a flat dollar co-pay that was the same dollar amount for generic as for brand drug purchases; (v) fully insured health plans, *i.e.*, Plans that purchased insurance from another Third Party Payor covering 100% of the Plan's reimbursement obligations for prescription drugs to its members; and (vi) insured individuals who purchased only branded Toprol XL (never generic metoprolol succinate) after the generic became available for the corresponding dosage. SA ¶ 1.

³ The Settlement Agreement references a confidential letter agreement granting Defendants the opportunity to withdraw from the Settlement if a certain percentage of Class members opt out of the proposed Settlement Class. SA ¶ 13. The terms that would trigger Defendants' right to withdraw are being kept confidential, which is a customary practice in cases of this nature. *See In re HealthSouth Corp. Sec. Litig.*, 334 Fed. App'x. 248, 250 n.4 (11th Cir. 2009). The parties will provide the side-letter agreement for *in camera* inspection upon request of the Court.

satisfied. *See id.* As demonstrated below, this Court should follow the lead of the many courts that routinely have certified indirect purchaser settlement classes asserting claims against drug manufacturers based on alleged anticompetitive practices.⁴

A. The Requirements Of Rule 23(a) Are Satisfied.

Numerosity. Under the numerosity requirement, the class must be large enough that joinder of all members would be “impracticable.” Fed. R. Civ. P. 23(a)(1). Here, public data produced in discovery revealed that there were tens of millions of prescriptions for Toprol-XL and its generic equivalent throughout the United States between 2005 and 2010. In light of these facts, it cannot seriously be disputed that joinder of all class members would be “impracticable.” *Id.* *See Remeron*, 2005 WL 2230314 at *8; *Relafen*, 231 F.R.D. at 68; *Cardizem CD*, 218 F.R.D. at 518.

Commonality: The commonality requirement of Rule 23(a)(2) requires that “there are questions of law or fact common to the class.” Courts have “consistently held that allegations of price-fixing, monopolization, and conspiracy by their very nature involve common questions of law or fact.” *Columbus Drywall & Insulation, Inc. v. Masco Corp.*, 2009 WL 856306, at *7 (N.D. Ga. Feb. 9, 2009). Antitrust claims involve common questions of law and fact because all class members’ injuries and claims arise from the same type of harm, namely, payment of overcharges as a result of anticompetitive conduct. This case is no different. *See First. Am. Consol. Compl.* (D.I. 276) ¶ 143 (identifying common questions).

⁴ *See, e.g., In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 246-52 (D. Del. 2002), *aff’d*, 391 F.3d 516, 531 (3d Cir. 2004); *In re Remeron End-Payor Antitrust Litig.*, 2005 WL 2230314 at *12 (D.N.J. Sept. 13, 2005); *Nichols v. SmithKline Beecham Corp.*, 2005 WL 950616, at *7 (E.D. Pa. Apr. 22, 2005); *In re Lupron Mktg. and Sales Practices Litig.*, 228 F.R.D. 75, 87-92 (D. Mass. 2005); *In re Relafen Antitrust Litig.*, 231 F.R.D. 52, 67-71 (D. Mass. 2005); *In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508 (E.D. Mich. 2003).

Typicality: Rule 23(a)(3) requires that the claims of the class representatives be typical of the claims of the class. In this case, the wrongful conduct alleged would have affected Plaintiffs and the Class in the exact same manner: all paid artificially inflated prices for Toprol-XL during the Class Period, and their claims will require proof of “the same elements the other class members would have to prove if they brought individual actions.” *In re Plastic Cutlery Antitrust Litig.*, 1998 WL 135703, at *4 (E.D. Pa. Mar. 20, 1998). Thus, typicality is easily satisfied here. *See also Warfarin*, 212 F.R.D. at 250 (typicality is satisfied where “the claims of the representative plaintiffs arise from the same course of conduct that gave rise to the claims of the other class members and are based on the same general legal theories”).

Adequacy: The final requirement of Rule 23(a) is that “the representative parties will fairly and adequately protect the interests of the class.” Fed. R. Civ. P. 23(a)(4). Throughout this litigation, Plaintiffs have demonstrated that they have the required “ability and incentive to represent the claims of the class vigorously.” *In re Cmty. Bank of N. Virginia*, 622 F.3d 275, 291 (3d Cir. 2010). They have fulfilled all of their duties in this litigation, including responding to discovery requests, producing documents, and sitting for depositions. Moreover, “there is no conflict between the individual’s claims and those asserted on behalf of the class,” *id.*, let alone the kind of conflict that might be an obstacle to class certification. *See In re Flat Glass Antitrust Litig.*, 191 F.R.D. 472, 482 (W.D. Pa. 1999) (a conflict is only disabling if it is “apparent, imminent, and on an issue at the very heart of the suit”) (citation omitted).

B. The Requirements Of Rule 23(b)(3) Are Satisfied.

Rule 23(b)(3) requires that the Court find (1) that common questions of law or fact predominate over individual questions; and (2) that a class action is superior to other available methods of adjudication. *See also Sullivan*, 667 F.3d at 298.

1. Common Legal and Factual Questions Predominate

The predominance requirement of Rule 23(b)(3) is readily satisfied here, as proof of Plaintiffs' claims is predominantly common to the class.

As many courts have noted, monopolization claims are particularly amenable to class certification because the proof focuses overwhelmingly on the defendant's conduct, and thus are proven with common evidence on which all Class members may rely. *See, e.g., Warfarin*, 391 F.3d at 528 (monopolization claim "naturally raise[d] several questions of law and fact common to the entire class and which predominate over any issues related to individual class members"); *In re Lorazepam & Clorazepate Antitrust Litig.*, 202 F.R.D. 12, 29 (D.D.C. 2001) ("As is true in many antitrust cases, the alleged violations of the antitrust laws at issue here respecting price fixing and monopolization relate solely to Defendants' conduct, and as such proof for these issues will not vary among class members.") (citation, internal quotes omitted). So too here: the focus of Plaintiffs' claims is Defendants' conduct – what AZ allegedly did and said before the PTO, the FDA and the courts – and its alleged impact – allegedly higher metoprolol succinate prices for all class members. *See generally* First. Am. Consol. Compl. (D.I. 276) ¶¶ 1-13.

Accordingly, courts within the Circuit and elsewhere routinely find that monopolization claims, such as those at issue here, involve predominantly common issues because they focus on the defendant's conduct and the well-established market-wide effects of impeding generic competition on drug prices. *See, e.g., In re Flonase Antitrust Litig.*, 2012 WL 2277840, at *10-26 (E.D. Pa. June 18, 2012); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213, 232 n.32 (D. Del. 2008) ("The Third Circuit also has recognized that monopolization and conspiracy claims involve predominantly common issues.") (citation omitted); *In re K-Dur Antitrust Litig.*, 2008 WL 2699390, at *11-20 (D.N.J. Apr. 14, 2008); *In re Neurontin Antitrust Litig.*, 2011 WL 286118, at *3-4 (D.N.J. Jan. 25, 2011); *In re Buspirone Patent Litig.*, 210 F.R.D. 43, 58

(S.D.N.Y. 2002) (“[p]roof of the allegedly monopolistic . . . conduct at the core of the alleged liability is common to the claims”); *Warfarin*, 212 F.R.D. at 248; *see also Sullivan*, 667 F.3d at 297 (affirming certification of settlement class of end-payors asserting claims brought pursuant to various state laws, and noting that any “concerns” about the propriety of certifying such claims “largely dissipate when a court is considering the certification of a settlement class”). The Court should reach the same conclusion here.

2. Superiority

Class treatment is superior to multiple individual actions. Indeed, courts consistently hold that class actions are a superior method of resolving antitrust claims. *See, e.g., In re Urethane Antitrust Litig.*, 237 F.R.D. 440, 453 (D. Kan. 2006) (noting that individual litigation of antitrust claims “would be grossly inefficient, costly and time consuming”). In directly analogous delayed generic entry cases, courts have held that class treatment is superior to, and more manageable than, any alternatives. *See, e.g., Remeron*, 2005 WL 2230314 at *12; *Warfarin*, 212 F.R.D. at 251.

C. The Court Should Appoint Class Counsel and Liaison Counsel

Plaintiffs respectfully request that the Court appoint Class Counsel to represent the Settlement Class. *See* Fed. R. Civ. P. 23(g)(1) (“[A] court that certifies a class must appoint class counsel.”). The firms representing Plaintiffs have extensive experience and expertise in antitrust and class action litigation.⁵ From the inception of this litigation, proposed Class Counsel have vigorously pursued this litigation and now have brought this matter to a favorable conclusion. This Court previously appointed the law firms of Kessler Topaz Meltzer & Check; Fine, Kaplan and Black; and Pomerantz Grossman Hufford Dahlstrom & Gross as interim Co-

⁵ More information about the proposed Co-Lead Counsel can be found on their respective firm websites: www.ktmc.com, www.finekaplan.com, and www.pomerantzlaw.com.

Lead Class Counsel, and Chimicles & Tikellis as interim Liaison Counsel. *See* Order of 4/5/06 (D.I. 13). These firms have provided more than adequate representation to the Class. Plaintiffs now respectfully request that the Court appoint them as Co-Lead Counsel and Liaison Counsel in accordance with Rule 23(g).

V. THE PROPOSED SETTLEMENT SHOULD BE PRELIMINARILY APPROVED

Approval of a class action settlement is a two-step process, the first involving preliminary approval of the settlement and procedural steps, *e.g.*, notice and a final fairness hearing, and the second being final approval of the settlement after a fairness hearing. *See, e.g., Gates v. Rohm & Haas Co.*, 248 F.R.D. 434, 438 (E.D. Pa. 2008).

At this first stage, a court need only make a preliminary evaluation as to whether the proposed settlement is within the range of possible approval and free of obvious deficiencies or reasons to doubt its fairness. *See Mehling v. New York Life Ins. Co.*, 246 F.R.D. 467, 472 (E.D. Pa. 2007); *Curiale v. Lenox Group, Inc.*, 2008 WL 4899474, at *4 (E.D. Pa. Nov. 14, 2008); *Thomas v. NCO Fin. Sys., Inc.*, 2002 WL 1773035, at *5 (E.D. Pa. July 31, 2002).

A. The Settlement Is Entitled To A Presumption Of Fairness.

There is an initial presumption of fairness and preliminary approval should be granted when the court finds: (1) a proposed settlement was negotiated at arm's length; (2) there was sufficient discovery; and (3) counsel is experienced in similar litigation. *In re Gen. Motors Corp. Pick-up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 786 (3d Cir. 1995); *In re Cendant Corp. Litig.*, 264 F.3d 201, 232 n.18 (3d Cir. 2001); *Varacallo v. Massachusetts Mut. Life Ins. Co.*, 226 F.R.D. 207, 235 (D.N.J. 2005). In addition, the court should consider that "there is an overriding public interest in settling class action litigation, and it should therefore be encouraged." *Warfarin*, 391 F.3d at 535.

As to the first factor, counsel engaged in diligent, arms'-length negotiations both with and without the assistance of a Court-appointed mediator. The discussions commenced in the fall of 2010 with an unsuccessful mediation session. After extensive discovery and motions practice, the Court-appointed mediator hosted a second mediation session in early April 2012. Those discussions led to further negotiations that were protracted, lasting several weeks, and involved multiple telephone calls that ultimately led to an agreement on the material terms of the settlement in late May 2012. Thereafter, the parties devoted several more weeks to negotiating the settlement agreement and its exhibits. During that process, the parties continued to vigorously represent their clients; discussions at one point reached an impasse on disputed issues, and they sought assistance from the Court-appointed mediator. Because the settlement discussions were principled and entirely at arm's length, this factor weighs in favor of granting preliminary approval. *See Milliron v. T-Mobile USA, Inc.*, 2009 WL 3345762, at *5 (D.N.J. Sept. 10, 2009) (“[T]he participation of an independent mediator in settlement negotiations virtually insures that the negotiations were conducted at arm's length and without collusion between the parties.”) (citation omitted), *aff'd*, 423 Fed. App'x. 131 (3d Cir. 2011).

Second, preliminary approval is warranted because Class Counsel have a great deal of experience in antitrust cases, including delayed generic entry antitrust cases such as this. Based on their thorough review of the record and careful analysis, Class Counsel believe the Settlement is fair, reasonable and adequate and merits Court approval. *See Collier v. Montgomery County*, 192 F.R.D. 176, 186 (E.D. Pa. 2000) (“[T]he court will give due regard to the advice of the experienced counsel in this case who recommend the settlement ... who have negotiated this settlement at arms-length and in good faith.”) (internal citation omitted); *Austin v. Pennsylvania Dep't of Corrections*, 876 F. Supp. 1437, 1472 (E.D. Pa. 1995) (“significant weight” should be

attributed “to the belief of experienced counsel that settlement is in the best interests of the class”) (citation omitted).

Third, the advanced stage of this litigation also supports preliminary approval. The Settlement was reached only after class certification was fully briefed, fact and expert discovery was complete, trial preparations were underway, and the parties were in the process of drafting the Joint Pre-Trial Order. Plaintiffs have reviewed and analyzed an extensive discovery record that includes more than one million pages of documents; more than two dozen deposition transcripts; and lengthy interrogatory responses. Moreover, Plaintiffs have litigated discovery disputes; researched and drafted numerous briefs and other filings; and worked at great length with economic, patent, pharmaceutical, and regulatory experts in preparation for class certification, summary judgment and trial. Substantive settlement talks only resumed after the close of fact and expert discovery and letters requesting summary judgment had been filed. Counsel had a thorough understanding of the merits before negotiations resumed in earnest.

In sum, there are no reasons to doubt the fairness of the Settlement. It is entitled to a presumption of fairness and it should be preliminarily approved.

B. The Settlement Falls Within The Range Of Possible Approval.

The proposed Settlement falls well within the range of settlements reached and approved in similar antitrust actions. *Cf. Mack Trucks, Inc. v. Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am.-UAW*, 2011 WL 1833108, at *3 (E.D. Pa. May 12, 2011) (granting preliminary approval where “the proposed settlement is fair and falls well within the range of reasonableness”); *Samuel v. Equicredit Corp.*, 2002 WL 970396, at *1 n.1 (E.D. Pa. May 6, 2002) (granting preliminary approval where the settlement “falls within the range of possible approval”) (citation omitted).

The cash payment of \$11 million is fair, reasonable and adequate, especially in light of the challenges presented by this litigation. Antitrust litigation generally involves complex issues of fact and law, and this case is no exception. While Plaintiffs have compiled compelling evidence supporting their allegations and theories, there can be no assurances in complex litigation, such as this, what the ultimate result might be before a jury. *See In re Packaged Ice Antitrust Litig.*, 2011 WL 717519, at *10 (E.D. Mich. Feb. 22, 2011) (“Experience proves that, no matter how confident trial counsel may be, they cannot predict with 100% accuracy a jury's favorable verdict, particularly in complex antitrust litigation.”) (citation omitted). To be sure, AZ consistently has denied liability in this matter, and would have asserted defenses at trial regarding both liability and damages. AZ would have argued that its conduct was proper, and that in any event delayed generic entry damaged Plaintiffs (if at all) much less than Plaintiffs contend. Consequently, Plaintiffs and AZ would have presented a jury with vastly different damage estimates. “Damages would likely be established at trial through a ‘battle of experts,’ with each side presenting its figures to the jury and with no guarantee whom the jury would believe.” *Warfarin*, 212 F.R.D. at 256 (internal quotations, citation omitted). The proposed Settlement enables Class members to receive the immediate benefit of a cash settlement while avoiding the risks inherent in facing summary judgment practice, a complex trial, and the lengthy appellate process. Given the risks presented, and considering the certain monetary recovery obtained in Settlement, the Settlement is worthy of preliminary approval.

Using the settlement in the related Direct Purchaser action as a benchmark, it is clear that the Settlement obtained here is fair, reasonable and adequate. In the Direct Purchaser class action, this Court approved a settlement providing for a cash payment of \$20 million plus up to \$750,000 for notice and claims administration, for a total of \$20.75 million. *See Meijer Inc. et*

al. v. AstraZeneca Pharm. LP et al., No. 06-52-MPT, D.I. 194 ¶ 2 (D. Del. Feb. 21, 2012) (final approval order). Here, the End-Payor settlement provides for a cash payment of \$10 million plus up to \$1 million for notice and claims administration, for a total of \$11 million. Accordingly, the End-Payor recovery viewed as a percentage of the Direct Purchaser recovery is 53% --- a benchmark that compares favorably to results obtained in other pharmaceutical end-payor antitrust cases. *See, e.g., In re Tricor Antitrust Litig.* (D. Del.) (indirects' settlement amount constituted 26% of directs' settlement amount)⁶; *In re Relafen Antitrust Litig.*, 231 F.R.D. 52, 83 (D. Mass. 2005) (indirects' settlement amount of \$75 million constituted 43% of directs' settlement amount of \$175 million); *In re Remeron Antitrust Litig.* (D.N.J.) (indirects' settlement constituted 47% of directs' settlement).⁷

The record shows that the proposed settlement is sufficiently within the range of fairness, adequacy and reasonableness to warrant preliminary approval and notice to the Class.

VI. THE NOTICE PROGRAM SHOULD BE APPROVED

A. Notice Plan Description

The proposed Notice Plan was designed with input from the proposed Settlement Administrator, Rust Consulting, Inc. ("Rust"), and its legal notice affiliate, Kinsella Media LLC ("Kinsella"). Rust has substantial experience in providing notice and administering settlements of pharmaceutical antitrust litigation, and Kinsella is a recognized leader in the legal notice

⁶ *See Painters Dist. Council No. 30 Health & Welfare Fund et al. v. Abbott Labs. et al.*, No. 05-360 (D. Del.), D.I. 504 at 2 (describing end-payor settlement for \$65.7 million) & D.I. 545 (final approval order); *Louisiana Wholesale Drug Co. et al. v. Abbott Labs. et al.*, Civ. No. 05-340 (D. Del.), D.I. 537 at 1 (describing direct purchaser settlement for \$250 million) & D.I. 543 (final approval order).

⁷ *See In re Remeron Direct Purchaser Antitrust Litig.*, 2005 WL 3008808, at *3 (D.N.J. Nov. 9, 2005) (\$75 million direct purchaser settlement); *In re Remeron End-Payor Antitrust Litig.*, 2005 WL 2230314 at *12 (D.N.J. Sept. 13, 2005) (end-payor settlement of \$35 million – a \$33 million settlement plus \$2 million for notice and administration costs).

field.⁸ Plaintiffs respectfully request that the Court appoint Rust to serve as the Settlement Administrator.

Interim Co-Lead Counsel developed the Notice Plan in close consultation with Kinsella's Dr. Shannon R. Wheatman, an expert specializing in the design and implementation of class action notices. *See* Wheatman Decl. (filed contemporaneously herewith). As summarized below, the proposed notice program has direct mail, internet and media publication components intended to reach potential Class members. *See id.* & Notice Plan (Wheatman's Decl. Ex. 2).

First, as soon as practicable after entry of the Preliminary Approval Order, a Postcard Notice in the form attached as Exhibit 7 to the Notice Plan will be sent via USPS First Class mail to the TPP members of the Settlement Class. The direct mail notice program will utilize Rust's proprietary list of 40,000 addresses for TPPs and their agents who may be members of the Settlement Class. *See* Notice Plan at 10-11.

Second, a notice substantially in the form attached as Exhibit 8 to the Notice Plan (the Consumer Publication Notice) shall be published in a variety of national publications that were specifically selected in order to reach adults who used a prescription drug to treat hypertension (high blood pressure) such as Toprol-XL and its generic equivalent. *See* Notice Plan at 12-13 & 23-27. The Consumer Publication Notice also will appear in an insert in nine newspapers published in the U.S. Territories. *Id.* at 14 & 29. In addition, a TPP Publication Notice (Ex. 8 to the Notice Plan) will appear in two industry trade journals, *HR Magazine* and *National Underwriter*. *See* Notice Plan at 13 & 28.

⁸ More information about Rust and Kinsella are available at their respective websites, www.rustconsulting.com and www.kinsellamedia.com.

Third, targeted internet banner ads will be published on a rotating basis for 30 days through three ad networks representing more than 6,000 websites. *Id.* at 30-31. Users who click on the ad will be directed to the Toprol-XL Settlement Website. *Id.* at 37.

Finally, a Press Release announcing the settlement will be issued to more than 5,550 print and broadcast outlets and 5,400 websites through PR Newswire. *See id.* at 38.

Using this national media delivery plan, an estimated 80% of high blood pressure medication user will have an opportunity to see the Notice. *Id.* at 32; Wheatman Decl. ¶ 24.

The Postcard Notice, TPP and Consumer Publication Notices, and Press Release provide a brief summary of the settlement and Class members' rights; the Toprol-XL Settlement Website address; contact information for the claims administrator and/or Class Counsel; a toll-free number to call for further information, and instructions on how to request a claim form and file a claim. Notice Plan at 39.

Finally, Rust will establish and maintain a Toprol-XL Settlement Website where Class members may obtain information about the Settlement and view and download a Detailed Notice in substantially the form attached as Exhibit 8 to the Notice Plan.⁹ *Id.* at 37. The Detailed Notices explain Class members' rights and options; describes Plaintiffs' claims, the litigation, the proposed Settlement and the Plan of Allocation; provides the complete Settlement Class definition and release; explains how to file a claim, object to the settlement, or seek exclusion from the Settlement Class; identifies Class Counsel and describes the forthcoming petition for an award of attorneys' fees, litigation costs, and incentive awards; provides information about the Fairness Hearing; and explains how to request additional information.

⁹ The Settlement Website also will make available for viewing and download the First Amended Consolidated Complaint; this Motion; the Settlement Agreement; the Allocation Plan; the Motion for Final Settlement Approval; Class Counsel's fee petition, and other case-related documents.

B. The Proposed Form And Manner Of Notice Are Appropriate

When a class action settlement is achieved, Rule 23(e) requires that the Court “direct notice in a reasonable manner to all class members who would be bound by the proposal.” *See also* Fed. R. Civ. P. 23(c)(2)(B) (notice of a certification order must be “the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort”). As described below, the notice program satisfies Rule 23 and is similar to those approved for notifying consumers and TPPs of other pharmaceutical antitrust class actions. *See also* Wheatman Decl. ¶¶ 34-35 (opining that the proposed notice program satisfies Fed. R. Civ. P. 23).

1. Notice to TPP Class Members

“It is well settled that in the usual situation first-class mail and publication in the press fully satisfy the notice requirements of both Fed. R. Civ. P. 23 and the due process clause.” *Zimmer Paper Prods., Inc. v. Berger & Montague P.C.*, 758 F.2d 86, 90 (3d Cir. 1985). In this case, direct mail to the comprehensive list of more than 40,000 addresses found in the proprietary Rust database, combined with publication notice in two industry trade journals, is the best notice practicable under the circumstances for TPPs. *See, e.g., Remeron*, 2005 WL 2230314, at *13) (approving similar TPP notice plan, including mailings “to all potential TPP class members included in CCS’ [Rust’s predecessor] proprietary TPP mailing database”); *VistaHealth Plan, Inc. v. Bristol-Myers Squibb Co.*, 287 F. Supp. 2d 65, 66 (D.D.C. 2003) (approving settlement where notice was mailed directly to third party payor class members and published in *National Underwriter*).

2. Notice to Consumer Class Members

Consumers will be notified of the proposed Settlement through a combination of summary notices appearing in major national publications and local newspapers, internet banner ads, a widely disseminated press release, and the Toprol-XL Settlement Website.

Individual notice is required where class members can be identified “through reasonable effort.” Fed. R. Civ. P. 23(c)(2)(B). Here, consumer class members cannot be identified through reasonable effort. Readily available mailing lists for prescription drug users do not exist because consumer class members’ health information is protected against disclosure under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-91. *See* 45 C.F.R. Part 160, and Part 164 Subparts A and E. Other avenues for obtaining consumer mailing lists proved either unavailing or cost-prohibitive. *See Larson v. AT&T Mobility*, 687 F.3d 109, 125 (3d Cir. 2012) (“In every case, reasonableness is a function of anticipated results, costs, and amount involved.”) (quoting *In re Nissan Motor Corp. Antitrust Litig.*, 552 F.2d 1088, 1098-99 (5th Cir. 1977)).¹⁰

¹⁰ Interim Co-Lead Counsel attempted to compile a partial mailing list for consumer Class members by soliciting the assistance of the largest third-party payors. Due to HIPAA and cost concerns, the large third-party payors declined to e-mail or mail notices to consumer Class members, or to provide a mailing list. Interim Co-Lead Counsel also sought AZ’s assistance, but unlike the defendants in *Larson* who had access to the names and addresses of their direct customers, persons prescribed Toprol XL and/or generic metoprolol succinate are not AZ’s direct customers and therefore Astra does not systematically collect or maintain contact information for them.

In some antitrust pharmaceutical cases with much larger settlement funds, plaintiffs have compiled consumer mailing lists by sending HIPAA-compliant subpoenas to pharmacies and health care providers seeking production of consumer purchase records and contact information. *E.g., Remeron*, 2005 WL 2230314, at *15 n.4. Here, given that there are thousands of pharmacies in the United States and potentially millions of consumers in the Class, the cost of compiling such information and mailing notices to identified consumers would consume an unreasonable portion – if not all – of the \$11 million settlement fund, with uncertain results. Given the “anticipated results, costs, and amount involved” here, *Larson*, 687 F.3d at 125, the cost of identifying consumers in this manner would be prohibitive and not in the best interests of the Class. *See Thomas v. NCO Fin. Sys., Inc.*, 2004 WL 727071, at *3 (E.D. Pa. Mar. 31, 2004) (“If the members of a putative class may not be determined by reasonable means, then constructive notice by publication may satisfy the requirements of Rule 23(c)(2).”).

Where, as here, class members cannot be identified through reasonable efforts, the Third Circuit has approved publication notice as a suitable alternative. In *In re Warfarin Sodium Antitrust Litigation*, a pharmaceutical antitrust class action similar to the instant matter, consumers who purchased the prescription drug Coumadin were notified of the proposed settlement by publication notice. Judge Robinson recognized that “individual notice was not reasonable or even possible to consumers,” and that the “best notice practicable under the circumstances was given by publishing the summary notice in newspapers and magazines which were likely to be read by potential class members....” 212 F.R.D. at 252. On appeal, the Third Circuit rejected an objector’s argument that individual notice should have been provided, noting that neither the plaintiffs nor the defendant had access to “the names and addresses of the multitude of people nationwide who purchased Coumadin because the identity of pharmaceutical purchasers is confidential information that cannot be disclosed....” *Warfarin Sodium*, 391 F.3d at 536-37.

Notably, as Dr. Wheatman explains, the publication notice plan proposed here is superior to the plan approved by the Third Circuit in *Warfarin*. Plaintiffs’ plan is more specifically targeted to class members while at the same time uses a broader variety of delivery vehicles, including the Internet. Under Plaintiffs’ Notice Plan, an estimated 80% of high blood pressure medication users will have an opportunity to see the Notice. *See* Wheatman Decl. ¶ 33; Notice Plan at 33. Because the proposed notice program is the best notice practicable under the circumstances, it should be approved.

3. The Form and Content of the Notices Should Be Approved

The Court also should approve the form and content of the proposed Postcard Notice, TPP Publication Notice, Consumer Publication Notice, and the Detailed Notices. As Dr.

Shannon Wheatman attests, the notices effectively communicate information about the Settlement and comport with the requirements of Rule 23. *See* Wheatman Decl. ¶¶ 30-32, 34-35.

For example, the Detailed Consumer Notice includes a plain English description of all of the elements required by Rule 23(c)(2)(B)(i)-(vii). *See* Notice Plan, Ex. 8. It fairly, clearly and concisely describes in plain, easily understood language:

- the nature of the action and the Class's claims (*see* questions 2-3), per Fed. R. Civ. P. 23(c)(2)(B)(i), (iii);
- the definition of the Settlement Class (*see* questions 4-6), per Fed. R. Civ. P. 23(c)(2)(B)(ii);
- that a Class member may object to the Settlement Agreement (*see* questions 14-16);
- that any Settlement Class member may appear in the action and be heard (*see* questions 21-22), per Fed. R. Civ. P. 23(c)(2)(B)(iv);
- that the Court will exclude from the Class any member who requests exclusion and the time and manner of requesting exclusion (*see* questions 12-13), per Fed. R. Civ. P. 23(c)(2)(B)(v)-(vi); and
- the binding effect of a class judgment on members of the Class (*see* question 11), per Fed. R. Civ. P. 23(c)(2)(B)(vii).

The Detailed Notice also outlines the terms of the proposed Settlement (*see* questions 1, 7-9); describes Class Counsel's request for attorneys' fees and reimbursement of all litigation expenses, and proposed incentive awards for each proposed Class Representative (*see* questions 17-18); includes the Toprol-XL Settlement Website address (*see* questions 7, 9, 11, 20, 23); and provides information about the Fairness Hearing (*see* questions 20-22). This information more than satisfies the requirements of Rule 23. *See In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 148 F.3d 283, 326-327 (3d Cir. 1998). *See also* Wheatman Decl. ¶ 34.

C. Proposed Schedule

Finally, the Notice informs Class members of the schedule for completing the settlement approval process, including the objection and opt-out deadlines, the submission of the motion for final approval of the Settlement, and the fairness hearing. A proposed schedule, in accordance with the notice requirements of the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1715, is set forth in proposed Preliminary Approval Order (Motion, Ex. 2).

VII. CONCLUSION

For the foregoing reasons, Class Counsel respectfully request that that Court grant the relief requested herein and enter the proposed Preliminary Approval Order.

DATED: September 25, 2012

CHIMICLES & TIKELLIS LLP



Pamela S. Tikellis (#2172)
A. Zachary Naylor (#4439)
P.O. Box 1035
222 Delaware Avenue, Suite 1100
Wilmington, DE 19801
(302) 656-2500

Liaison Counsel for Indirect Class Plaintiffs

Joseph H. Meltzer
Terence S. Ziegler
**KESSLER TOPAZ MELTZER &
CHECK, LLP**
280 King of Prussia Road
Radnor, PA 19087
Tel.: (610) 667-7706
Fax: (610) 667-7056

Jeffrey S. Istvan
Paul Costa
FINE, KAPLAN AND BLACK, R.P.C.
1835 Market St., 28th Floor
Philadelphia, PA 19103

Tel.: (215) 567-6565

Fax: (215) 568-5872

Michael M. Buchman

Adam G. Kurtz

POMERANTZ GROSSMAN HUFFORD

DAHLSTROM & GROSS LLP

600 Third Avenue

New York, NY 10016

Tel: (212) 661-1100

Fax: (212) 661-8665

Interim Co-Lead Counsel for Indirect Class Plaintiffs